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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,944	02/26/2004	William R. Patterson	355492-3100	5793
38706	7590	10/26/2007		
FOLEY & LARDNER LLP 1530 PAGE MILL ROAD PALO ALTO, CA 94304			EXAMINER ROGERS, JAMES WILLIAM	
			ART UNIT 1618	PAPER NUMBER
			MAIL DATE 10/26/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/789,944	Applicant(s) PATTERSON ET AL.	
	Examiner James W. Rogers, Ph.D.	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9-13 and 15-51 is/are pending in the application.
- 4a) Of the above claim(s) 1-6,17-19,21-35 and 48-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7,9-13,15,16,20,36,38-47 and 51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>9/21/2007</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment to the claims filed 10/12/2007 has been entered. Applicants have canceled claims 8,14 and 37 added new claim 51 and amended claims 7,9-13, 15-20, 36 and 38-50. Any rejection from the previous office action filed 06/29/2007 not addressed in the office action below has been withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7,9-13,15-16,20,36 and 38-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Unger et al. (US 6,139,819), for the reasons set forth in the office action filed 06/29/2007.

Response to Arguments

Applicant's arguments filed 09/19/2007 have been fully considered but they are not persuasive.

Applicants assert that Unger does not disclose whether the amount of viscosity modifier is an affective amount to impart shear thinning and pseudo-plastic properties to the composition. Applicants also assert that Unger does not mention sterilizing the composition and its impact on the thixotropic behavior. Applicants further assert that it is

not inherent that the shelf life of the compositions of Unger will be the same as their claimed invention and point to [0020] of their own specification as evidence.

The relevance of these assertions is unclear. Clearly any amount of viscosity modifier is capable of having some effect to on shear thinning and give some pseudo-plastic properties to the composition. Applicants have not met their burden of demonstrating that the amount of rheological modifier used within Unger will not demonstrate at least some of the above properties on the compositions recited. In regards to applicants assertion that Unger does not teach sterilizing the composition, firstly heat or irradiation is considered by the examiner to be a **product by process** type of limitation on the **preamble** of the claim, ("where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation"); *Kropa v. Robie*, 187 F.2d at 152, 88 USPQ2d at 480-81. With regard to product by process claim(s), the product disclosed by the prior art is identical to the claimed product, even though (it is made by a somewhat different process/the prior art is silent on the method of making). There is no evidence to show that the claimed process imparts any patentable distinction between the claimed product and that of the prior art. It is also inherent that since the compositions of Unger are administrable by injection they would have to be sterilized prior to injection. Regarding the shelf life of the Unger compositions, applicant's claims clearly overlap in scope with the compositions of Unger, since the two compositions are essentially the same it is inherent that such a composition will have the same properties including shelf life. It appears as though applicants are attempting

to claim a new function or property of an old composition. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 7,9-13,15-16,20,36,38-47 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Unger et al. (US 6,139,819, cited previously) in view of Greff et al. (US 5,580,568) in view of Porter et al. (US 2003/0039696 A1, cited previously), this new rejection was necessitated by applicants amendments to the claims and new claim 51.

Unger is disclosed in the previous office action and above. Unger is silent on the type of sterilization treatment and Unger is silent on the rheological modifying agents as claimed within new claim 51.

Greff was disclosed in the previous office action. Greff is used primarily for the disclosure within that it was already well known in the art that embolic compositions were heat sterilized. See col 5 lin 40-48. It would have been obvious to one skilled in the art that heat could have been used to sterilize the composition of Unger since the compositions of both the references above are related to the same field of endeavor, embolic compositions. The motivation to sterilize an embolic composition would obviously be to kill or eliminate any transferable agents (bacteria, viruses) so that the agents would not be introduced directly into the bloodstream when the composition is injected to a subject in need.

Porter was disclosed in the previous office action. Porter is used primarily for the disclosure within that rheology modifying agents were already well known in the art at the time of applicant's invention to be useful in embolic compositions. It would have been prime facie obvious at the time of the invention to a person of ordinary skill in the art to modify the embolic composition disclosed in Unger and add the rheological modifying agents disclosed within Greff. It is generally considered to be prime facie obvious to combine compounds each of which is taught by the prior art to be useful for the same purpose in order to form a composition that is to be used for an identical purpose. The motivation for combining them flows from their having been used individually in the prior art, and from them being recognized in the prior art as useful for the same purpose. As shown by the recited teachings, instant claims are no more than the combination of conventional components found within embolic compositions. It therefore follows that the instant claims define prime facie obvious subject matter.

Conclusion

No claims are allowed at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP §706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the


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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 271-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER